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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,328	04/12/2001	Bernhard Laemmle	R-247.00CIP	3484
7590 12/16/2004				
Baxter Healthcare Corporation				
P.O. Box 15210				
Irvine, CA 92614				
EXAMINER				
WALICKA, MALGORZATA A				
ART UNIT		PAPER NUMBER		
1652				

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/833,328

Applicant(s)

LAEMMLE ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-21 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-21,23-26 and 29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The Amendment filed Sept. 24, 2004 is acknowledged. Claims 1-6, 8-21 and 23-35 are pending. Claim 1, 12, 17, 25, 26, 29 are amended; claims 7 and 22 have been canceled. Claims 27-28 and 32-35 have been withdrawn from consideration as drawn to the non-elected invention. Claims 1-6, 8-21, 23-26, 29-31 are the subject of this Office Action.

DETAILED ACTION

1. Objections

The paper copy of the sequence listing of Dec.24 2001 contains printing errors in numbering nucleotides of SEQ ID NO: 3 specifically. Please provide a corrected copy of the paper sequence listing together with the statement of sameness of the Computer Readable Form filed on January 24, 2002.

2. Rejections

2.1. 35 USC section 112, second paragraph

Rejection of claim 29 made in the Office Action of June 19, 2004 is moot because the claim has been canceled.

2.2. 35 USC section 112, first paragraph

Rejection of claims 7 and 22 is moot because the claims have been canceled.

Claims 1-6, 8-11, 13-21, 23-26 and 29-31 are still rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The

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claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a polypeptide, composition or a complex comprising said polypeptide, having molecular weight from about 180 kD to 120 kD as determined by SDS-PAGE electrophoresis under reduced conditions and comprising the amino acids sequence of SEQ ID NO: 1. The claims are directed to a large and variable genus of polypeptides whose function and structure is not sufficiently described in the disclosure. The specification teaches several species of the claimed genus, i.e., polypeptides having molecular weight 180 kD, 170, 160 and 120 kD and comprising the amino acids sequence of SEQ ID NO: 1 whose function is cleavage of vWF. The specification, however, does not teach the function of other polypeptides having molecular weight between 180 kD and 120 kD and comprising the amino acids sequence of SEQ ID NO: 1. Disclosure of several species of the claimed genus is insufficient to put one skilled in the art in possession of all the species of claimed genus, because the function/structure relationship for the disclosed polypeptides is unknown. Applicants disclose polypeptides having molecular weight 180 kD and 120 kD and comprising the amino acids sequence of SEQ ID NO: 1 whose function is cleavage of vWF but no description has been provided of the common functional features of all polypeptides encompassed by the genus of the claims. No information, beyond the characterization of SEQ ID NO: 1 and 4 and molecular weight of several bands has been provided by applicants, which would indicate that they had possession of the

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claimed genus of polypeptides. The claimed genus is diverse in its structure and only several representative species having biological function are disclosed by Applicants. These species are not a representative of all members of the entire genus of polypeptides claimed, and are not sufficient to provide the identifying structural/functional characteristics of the other members of the genus. The disclosure is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.

In summary, the claimed polypeptides are insufficiently described in the disclosure, and one skilled in the art cannot reasonably conclude that the Applicants had possession of the claimed invention at the time the instant application was filed.

In their Remarks of September 20, 2004, Applicants argue, "Applicants submit the Examiner's rejection presupposes that other proteins exist that lie within the recited size range and comprise SEQ ID NO:1. Because the Examiner has not provided any evidence such proteins exist, Applicants submit the Examiner has not established a *prima facie* case", page 12, first paragraph.

Applicants argument has been fully considered but is found not persuasive for the following reasons. It is not that the Examiner presupposes that "other proteins exist that lie within the recited size range", but it is exactly what is claimed. Claim 1 is directed to "A composition exhibiting vWF protease activity comprising at least one single isolated peptide chain having a molecular weight from about 180 kD to about 120

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kD as determined by SDS-PAGE under reducing conditions and comprising the amino acid sequence AAGGILHLELLV(SEQ ID NO 1.”

Thus the language of the claim refers to a continuum of peptides, i.e. extremely large number of polypeptides (a polypeptide chain is just a polypeptide) having molecular weight in the range 180 kD-120 kD under reducing conditions, exhibiting vWF protease activity and comprising SEQ ID NO: 1. Applicants do not disclose such large number of polypeptide. In the table on page 23 Applicants teach only four polypeptide bands separated by SDS-PAGE under reduced conditions. These bands, with molecular weight of 180 kD, 170 kD, 160 kD and 120 kD comprise SEQ ID NO:1. There is no other bands within the range of 180 kD-120 kD under reducing conditions disclosed in Table on page 23. Thus, it is not that the examiner presupposes that other proteins exist that lie within the recited size range, but the Applicants claim what they did not disclose.

2.3. 35 USC section 102

Claims 1-26, and 29-31 were rejected under 35 U.S.C. 102(b) as being anticipated by Furlan et al. (Partial Purification and Characterization of a Protease from Human Plasma Cleaving von Willebrand Factor to Fragments Produced by *in Vivo* Proteolysis, Blood, 1996, 87/10, 4223-4234). The rejection of claim 7 and 22 is moot because the claims have been canceled. Rejection of claims 1-6, 8-21, 23-26 and 29-31 is withdrawn in the light of Applicants arguments and after reconsideration of teachings of the prior art.

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Specifically, the rejection is withdrawn, because Furlan et al. isolated their proteins using different method than that used by the instant application and Gerritsen et al. In addition, under reducing conditions, Furlan et al. did not obtain the bands with molecular weight of 180 kD, 170 kD, 160 kD and 120 kD as recited by amended claims. Furlan et al. point out, "After disulfide reduction, the strongest Coomassie staining was associated with polypeptide bands of 65 and 50 kD, and only a small of total protein migrated with and M_r greater than 80 kD, see page 4228, right column, line 9.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (571) 272-0944 and the right fax number is (571) 273-0944. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. EST.

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If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

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Patent Examiner


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1600